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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/559,852

12/07/2005

Albert Kudzovi Amegadzie

X-15590

7461

25885

7590

11/12/2008

ELI LILLY & COMPANY

PATENT DIVISION

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EXAMINER

SHTERENGARTS, SAMANTHA L

ART UNIT

PAPER NUMBER

1626

NOTIFICATION DATE

DELIVERY MODE

11/12/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary	Application No. 10/559,852	Applicant(s) AMEGADZIE ET AL.	
	Examiner Samantha L. Shterengarts	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 17 and 18 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21 is/are allowed.
- 6) ☒ Claim(s) 1-13 and 16 is/are rejected.
- 7) ☒ Claim(s) 14 and 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7 Dec 05, 21 Aug 07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. The instant application is a national stage entry of PCT/US04/15579, filed June 3, 2004, which claims priority to U.S. Provisional Application No. 60/477,885, filed June 12, 2003.

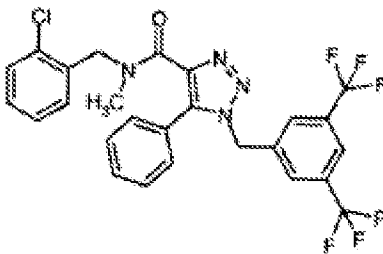
Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on December 7, 2005 and August 21, 2007 were in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. The IDS documents were considered. A signed copy of each form 1449 is enclosed herewith.

Election/Restrictions

3. Applicant's election without traverse of Group I, encompassed by Claims 1-16 and 21 in the reply filed on August 11, 2008 is acknowledged.

4. As per MPEP 803.02, the Examiner will determine whether the entire scope of the claims is patentable. Applicants' elected species of the following compound (Example 100):



makes a contribution over the prior art of record. Therefore, according to MPEP 803.02: should the elected species appear allowable, the search of the Markush-type claim will be extended. If the search is extended and a non-elected species is not found allowable, the Markush-type claim shall be rejected and claimed to the nonelected invention held withdrawn from further

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consideration. The search of the Markush-type claim has been extended to include all of the products of the Formula (I).

Specification

5. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Content of Specification

- (a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

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- (b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.
- (c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.
- (d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).
- (e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.
- (f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:
 - (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
 - (2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."
- (g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.
- (h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

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- (i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).
- (k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).
- (l) Sequence Listing. See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4 are rejected under 35 U.S.C. 102(a) as being anticipated by Katriyzky et al.

[Katritzky, Alan R. Synthesis of C-Carbamoyl-1,2,3-triazoles by Microwave-Induced 1,3-Dipolar Cycloaddition of Organic Azides to Acetylenic Amides. *Journal of Organic Chemistry*, 67 (2002) 9077-9079.]

Compounds 9a and 10a on page 9078 anticipated instant claims 1-4.

7. Claims 1-4 are rejected under 35 U.S.C. 102(a) as being anticipated by Katriyzky et al.

[Katritzky, Alan R. "1,3-Dipolar cycloaddition of organic azides to ester or benzotriazolylcarbonyl activated acetylenic amides." *ARKIVOC*, 15 (2003) 47-55.]

Compounds 21a, 21b, 21c, and 21d, on page 55 anticipate instant claims 1-4.

8. Claims 1-4 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Dorwald et al. [WO 97/40025].

Compound 2 on page 24 and compound 1 on page 25 of the specification anticipate instant claims 1-4. Additionally, Dorwald et al. teaches pharmaceutical compositions against specific receptors and enzymes.

Claim Rejections - 35 USC § 103

9. Claims 1-13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Amegadzie et al. (U.S. Patent No. 7, 179, 804).

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Determining the scope and contents of the prior art

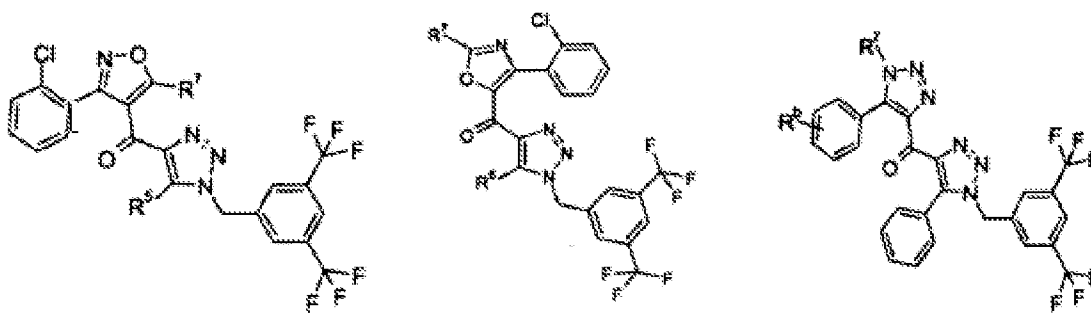
Amegadzie et al. teaches different positional isomers of the instantly claimed compounds.

Ascertaining the differences between the prior art and the instantly claimed invention

Amegadzie et al. teaches various positional isomers of the instantly claimed compounds.

The examples in the specification show a structure where the R² and R³ substituents of the instant claims and the R⁴ substituent of U.S. Patent No. 7, 179, 804 have a different connectivity, a nitrogen versus carbon; however, these are considered positional isomers because these substituents are at different positions from the carbonyl or sulphonyl group of D⁴.

Examples (does not include all positional isomers in the reference specification):

Resolving the level of ordinary skill in the pertinent art - Prima facie case of obviousness

MPEP 2144.09.II. states, "Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH₂- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. In re Wilder, 563 F.2d 457, 195USPQ 426 (CCPA 1977).

In positional isomerism, a functional group changes position on the chain or ring. As

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claimed, these two positional isomers have identical intended uses as well. As stated in *In re Norris* 179 F.2d 970, 84 U.S.P.Q. 458 (C.C.P.A. 1970), a novel useful compound that is isomeric with the prior art compound is unpatentable unless it possesses some unobvious or unexpected beneficial property not possessed by the prior art compound. In other words, if the positional isomers of the instant application produced unexpected results that would not be obvious to one of ordinary skill in the art, they would be patentably distinct; however, there is no evidence of such results in the instant application.

Thus, the instant claims are *prima facie* obvious over the prior art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-13 and 16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 and 16 U.S. Patent No. 7, 179, 804. Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons below.

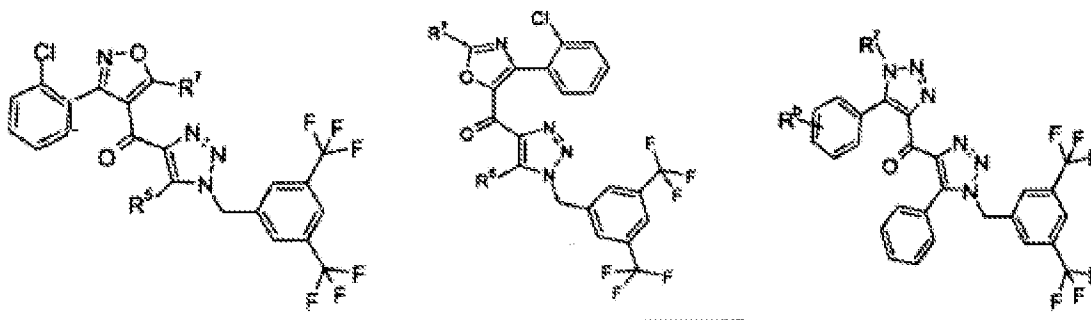
Determining the scope and contents of Claims 1-13 and 16 of U.S. Patent No. 7, 179, 804

Claims 1-13 and 16 of U.S. Patent No. 7, 179, 804 disclose numerous positional isomers of the instant claims.

Ascertaining the differences between Claims 1-13 and 16 of U.S. Patent No. 7, 179, 804 and instant claims 1-13 and 16

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Amegadzie et al. teaches various positional isomers of the instantly claimed compounds. The examples in the specification show a structure where the R² and R³ substituents of the instant claims and the R⁴ substituent of U.S. Patent No. 7, 179, 804 have a different connectivity, a nitrogen versus carbon; however, these are considered positional isomers because these substituents are at different positions from the carbonyl or sulphonyl group of D⁴. Examples (does not include all positional isomers in the reference specification):



Resolving the level of ordinary skill in the pertinent art – Prima Facie Case of Obviousness

Positional isomers are generally of sufficiently close structural similarity because there is a presumed expectation that such compounds possess similar properties. MPEP §2144.09, *Ex parte* Henkel 130 USPQ 474, (1-phenyl-3-methyl-4-hydroxypyrazole) obvious over reference teaching (3-phenyl-5-methyl-4-hydroxypyrazole). *Ex parte* Weston, 121 USPQ 429.

One of ordinary skill would be motivated to make the positional modifications required to arrive at the instant invention with reasonable expectation for success of obtaining a compound that is active for the treatment of a condition associated with an excess of tachykinins. Examiner expects the positional isomers would retain the activity of the instantly claimed compounds, especially since the disclosure of both the instant application and U.S. Patent 7,179,804 uses these compounds for the same utility. It is obvious to one of ordinary skill to

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make this modification with reasonable expectation for success. The motivation to make this modification would be to make alternate compounds for the quoted purpose.

Claim Objections

11. Claims 14-15 are objected to for depending on a rejected base claim.

Conclusion

12. Claim 21 is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samantha Shterengarts whose telephone number is (571)270-5316. The examiner can normally be reached on Monday thru Thursday 9-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samantha L. Shterengarts/
Examiner, Art Unit 1626

/Kamal A Saeed/
Primary Examiner, Art Unit 1626